MRN:_____

DOB:_____

STANDARD Actemra® (tocilizumab) PLAN OF TREATMENT FOR GIANT CELL ARTERITIS

NOTE: Patient ***may be ineligible*** to receive tocilizumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new-onset or deterioration neurological changes, new-onset abdominal symptoms, and/or surgery.

1. Patient Name:_____ Height (inches):_____ Weight (lbs):_____

2. Allergies:_____

3. Diagnosis:

□ M31.6 Other Giant Cell Arteritis □ M31.5 Giant cell arteritis with polymyalgia rheumatica

□ Other **ICD-10 Code**:_____ **diagnosis description:** _____

4. Pre-medications: *Administered 30 minutes prior to infusion as selected:*

**** Suggest caution with use of Diphenhydramine due to 60-minute infusion time and safety risks with driving.***

Acetaminophen:
- □ 650 mg PO
- □ 500 mg PO
- □ 325 mg PO

Diphenhydramine: □ 25 mg PO, □ 50 mg PO, □ 25 mg IVP, □ 50 mg IVP or
Fexofenadine □ 60 mg or □ 180 mg, □ Cetirizine 10 mg, □ Loratadine 10 mg
Methylprednisolone □ 40 mg IVP □ 125 mg IVP or other_____mg IVP
Famotidine: □ 20 mg PO, □ 40 mg PO, □ 20 mg IVP, □ 40 mg IVP

Pre-medicate with other: _____

5. Order:

Actemra® (tocilizumab) 6mg/kg per 100ml NS IV to infuse over 1 hour every 4 weeks

**** ACTEMRA® dosing exceeding 600 mg is not recommended in patients with GCA***

Lab orders: (Initial labs should be drawn prior to first infusion and then routinely)

CBC with diff, Platelets, and LFT's to include ALT and AST: at 2nd infusion, and then every 12 weeks with infusions
Cholesterol level at 2nd infusion, and then every 6 months

Lab parameters for treatment: (Pharmacist to perform clinical lab monitoring)
If ANC>1000 cells/mm^3 maintain dose. If ANC is 500 to 1000 cells/mm^3, interrupt tocilizumab dosing. When ANC >1000 cells/mm^3, resume tocilizumab at 4mg/kg and increase to 8mg/kg as clinically appropriate. If ANC < 500 cells/mm^3, then discontinue tocilizumab.
If Platelet count 50,000 to 100,000 cells/ mm^3, then interrupt tocilizumab dosing. When platelet count is > 100,000 cells/ mm^3, resume treatment at tocilizumab at 4mg/kg and increase to 8mg/kg as clinically appropriate. If Platelet count is <50,000 cells/ mm^3, then discontinue tocilizumab.
If Liver enzymes are > 3-5 x upper limit normal or ALT/AST are > 1.5x upper limit normal, then HOLD dose of tocilizumab.
If Cholesterol levels are elevated, notify referring MD for clinical evaluation and monitoring.

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES
If anaphylaxis or other hypersensitivity reaction occurs, stop administration immediately and discontinue permanently.
Do not administer to patients with known hypersensitivity.

6. Physician's Signature:_____/_____ Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials:_____ NPI: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders

MRN:_____

DOB:_____

Guidelines for Prescribing Actemra ® (tocilizumab)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

☐ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*

☐ Include patient demographic information and insurance information. (Copy of insurance cards if available)

☐ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- ACTEMRA® (tocilizumab) is indicated for the treatment of giant cell arteritis (GCA) in adult patients.

☐ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Actemra® as specified of_____weeks. Last known biological therapy:_____and last date received:_____. (Include copy of last ACTEMRA® infusion record if available and currently on therapy)

☐ Other as requested: _____

_____

_____

Required Pre-Screening:

☐ **TB screening test completed. Results** (positive or negative): _____

☐ **Hepatitis B screening test completed. Results** (positive or negative): _____

*If TB or Hep B results are positive, please send documentation of treatment or medical clearance.

☐ **Lab results within last 30-60 days: CBC with diff, Platelets, both AST and ALT, and Cholesterol level.** (It is recommended that tocilizumab not be initiated in patients with an ANC of less than 2000/mm^3, platelet count below 100,000/mm^3, or who have ALT or AST greater than 1.5 x the upper limit of normal.)

** Warnings/Precautions: **Hypersensitivity Reactions, Including Anaphylaxis:** If anaphylaxis or other hypersensitivity reaction occurs, stop administration immediately and discontinue permanently. Do not administer to patients with known hypersensitivity. **Serious infections**: leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving ACTEMRA®. Pre-screening for TB prior to starting ACTEMRA. Safety and efficacy has not been studied in patients with hepatic impairment, including patients with positive HBV and HCV serology. Consider interrupting therapy with Actemra® if patients develop a new infection during treatment. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Actemra ® has not been studied in combination with other biologics. **Gastrointestinal (GI) perforation:** Events of gastrointestinal perforation have been reported in clinical trials, primarily as complications of diverticulitis in RA patients. Use caution in patients who may be at increased risk or history of diverticulitis/GI Bleed. Evaluate patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation. ***Laboratory monitoring*** – recommended due to potential consequences of treatment-related changes in neutrophils, platelets, lipids, and liver function tests. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with Actemra ®. See full prescribing information

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.